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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/525,808 03/15/00 ANAGNOSTOU

A 5218-39C

020792 HM22/1023  
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EXAMINER

HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/23/01

*9*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/525,808

Applicant(s)

ANAGNOSTOU ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 16-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Upon further consideration, the restriction requirement set out in Paper No. 3, mailed 4/11/2001, is withdrawn.

Claims 16-29 are pending and examined on the merits.

### ***Claim Rejections - 35 USC § 112***

2. Claims 23-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The basis for this rejection is that newly submitted claim 23 introduces new matter into the specification.

New claim 23, and dependent claims 24-29, are drawn to methods of treating endothelial injury comprising administering erythropoietin, wherein the erythropoietin is administered in an amount from about 100 Units per kilogram to about 200 Units per kilogram. Applicant fails to show where support for the dosage limitation may be found in the specification. The specification only provides in vitro data as support for the claimed methods. Thus, the concentrations taught in the specification are not relevant to in vivo dosage limitations recited in claim 23 and one may not readily envisage the specific range of 100 Units to 200 Units per kilogram from any of the teachings in the specification. Therefore, it would appear that

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applicant was not in possession of the claimed methods, where the methods are limited to administration of a specific range of dosages of erythropoietin, at the time the invention was filed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 16-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Kuriyama et al (Kuriyama, S. et al., American Journal of Hypertension, 9: 426-431, 1996, May).

Claims 16-22 are drawn to methods of treating endothelial injury comprising administering erythropoietin to subjects in need of treatment for endothelial injury. Claims 16-29 are drawn to methods of treating endothelial injury, where the injury is caused by mechanical damage, exposure to radiation, inflammation, heart disease or cancer. The cause of the injury is not accorded patentable weight on the claimed methods because each of the methods comprises the same step, a step of administering erythropoietin. Claim 22 recites the limitation that the erythropoietin is administered intravenously.

Kuriyama teaches a method of administering recombinant human erythropoietin to dialysis patients, and teaches that erythropoietin administration decreases Tm levels in dialysis patients. Kuriyama teaches that a rise in Tm level is indicative of endothelial cell damage, and

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teaches that the decrease in Tm levels was probably due to an improvement in endothelial cell function (page 429-430). Thus, Kuriyama teaches a method of treating endothelial cell injury comprising administering an endothelial-protecting amount of erythropoietin to subjects suffering from endothelial cell injury.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuriyama et al.

Claims 23-29 are drawn to the same methods as the methods of claims 16-22, except that the specific dosage range of 100 Units per kilogram to 200 Units per kilogram is included in the claimed methods. Reciting a dosage range does not serve to distinguish the claimed methods over the prior art because it is well within the skill of one of ordinary skill in the art to optimize dosage levels of pharmaceutical compositions. Thus, claims 23-29 are obvious over the teachings of Kuriyama as set forth above.

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*Conclusion*

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran  
Patent Examiner  
October 21, 2001

  
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